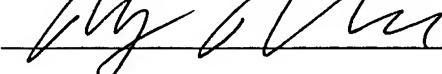




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By:  Printed: ~~Nadine Tono~~ Amy Alwine

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
Alza Corporation  
  
Inventor(s): Martin et al.  
  
Application No.: 10/616,094  
  
Filed: July 8, 2003  
  
Title: THERAPEUTIC LIPOSOME  
COMPOSITION AND METHOD

Group Art Unit: 1636  
  
Examiner:  
KATCHEVES, Konstantina T.  
  
Attorney Docket No.:  
**SQ00151USCON2**

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P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

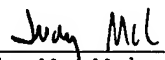
☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☒ There are no listed references which are not in the English language.

☒ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750.

Respectfully submitted,

  
\_\_\_\_\_  
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STATEMENT BY APPLICANT**

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Sheet 1 of 3

<b>Application Number</b>	10/616,094
<b>Filing Date</b>	July 8, 2003
<b>First Named Inventor</b>	Martin et al.
<b>Group Art Unit</b>	1636
<b>Examiner Name</b>	KATCHEVES, Konstantina T.
<b>Attorney Docket Number</b>	SQ00151USCON2

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
	1	4,935,465		Garman	06/19/1990	
	2	5,013,556		Woodle et al.	05/07/1991	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
	3	EP	0 317 957	B1	Senter	05/31/1989		
	4	WO	94/21281	A1	Zalipsky et al.	09/29/1994		
	5	EP	0 526 700	B1	Tagawa et al.	02/10/1993		

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	6	ALLEN et al., "A new strategy for attachment of antibodies to sterically stabilized liposomes resulting in efficient targeting to cancer cells", <i>Biochimica et Biophysica Acta</i> 1237 (1995); pp. 99-108	
	7	ANWER et al., "Optimization of Cationic Lipid/DNA Complexes for Systemic Gene Transfer to Tumor Lesions", <i>Journal of Drug Targeting</i> Vol. 8, No. 2 (2000); pp. 125-135	
	8	BALDWIN et al., "Effect on Polymyxin B on Experimental Shock from Meningococcal and Escherichia coli Endotoxins", <i>The Journal of Infectious Diseases</i> 164 (1991); pp. 542-549	
	9	BLUME et al., "Specific targeting with poly(ethylene glycol)-modified liposomes: coupling of homing devices to the ends of the polymeric chains combines effective target binding with long circulation times", <i>Biochimica et Biophysica Acta</i> 1149 (1993); pp. 180-184	
	10	BONE, "The Pathogenesis of Sepsis", <i>Annals of Internal Medicine</i> 115 (1991); pp. 457-469	
	11	CAPON and WARD, "THE CD4-gp120 INTERACTION AND AIDS PATHOGENESIS", <i>Annual Review of Immunology</i> 9 (1991); pp. 649-678	
	12	DEFREES et al., "Sialyl Lewis x Liposomes as a Multivalent Ligand and Inhibitor of E-Selectin Mediated Cellular Adhesion", <i>Journal of the American Chemical Society</i> 118 (1996); pp. 6101-6104	
	13	DINARELLO, "Interleukin-1 and Interleukin-1 Antagonism", <i>Blood</i> Vol. 77, No. 8 (1991); pp. 1627-1652	
	14	FRIEDMANN, "Overcoming the Obstacles to Gene Therapy", <i>Scientific American</i> (1997); pp. 96-101	

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Application Number	10/616,094
Filing Date	July 8, 2003
First Named Inventor	Martin et al.
Group Art Unit	1636
Examiner Name	KATCHEVES, Konstantina T.
Attorney Docket Number	SQ00151USCON2

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	15	HAYNES, "Scientific and Social Issues of Human Immunodeficiency Virus Vaccine Development", Science 260 (1993); pp. 1279-1286	
	16	HEATH et al., "Covalent Attachment of Immunoglobulins to Liposomes Via Glycosphingolipids", Biochimica et Biophysica Acta 640 (1981); pp. 66-81	
	17	HUMPHRIES et al., "A Synthetic Peptide from Fibronectin Inhibits Experimental Metastasis of Murine Melanoma Cells", Science 233 (1986); pp. 467-470	
	18	ICHIKAWA et al., "Chemical-Enzymatic Synthesis and Conformational Analysis of Sialyl Lewis x and Derivatives", Journal of the American Chemical Society 114 (1992); pp. 9283-9298	
	19	KANO et al., "THE ACTIVATION OF cAMP-DEPENDENT PROTEIN KINASE IS DIRECTLY LINKED TO THE INHIBITION OF OSTEOBLAST PROLIFERATION (UMR-106) BY PARATHYROID HORMONE-RELATED PROTEIN", Biochemical and Biophysical Research Communications Vol. 179, No. 1 (1991); pp. 97-101	
	20	KAWASAKI et al., "Amino Acids and Peptides.XIV. Laminin Related Peptides and Their Inhibitory Effect on Experimental Metastasis Formation", Biochemical and Biophysical Research Communications Vol. 174, No. 3 (1991); pp. 1159-1162	
	21	KIRPOTIN et al., "Liposomes with detachable polymer coating: destabilization and fusion of dioleoylphosphatidylethanolamine vesicles triggered by cleavage of surface-grafted poly(ethylene glycol)", FEBS Letters 388 (1996); pp. 115-118	
	22	KLIBANOV and HUANG, "Long-Circulating Liposomes: Development and Perspectives", Journal of Liposome Research Vol. 2, No. 3 (1992); pp. 321-334	
	23	MARTIN et al., "Immunospecific Targeting of Liposomes to Cells: A Novel and Efficient Method for Covalent Attachment of Fab' Fragments via Disulfide Bonds", Biochemistry 20 (1981); pp. 4229-4238	
	24	MARTIN and PAPAHAJDIOPOULOS, "Irreversible Coupling of Immunoglobulin Fragments to Preformed Vesicles", Journal of Biological Chemistry Vol. 257, No. 1 (1982); pp. 286-288	
	25	MARTIN, "Pharmaceutical Manufacturing of Liposomes", Chapter 6, Specialized Drug Delivery Systems: Manufacturing and Production Technology (Marcel Dekker, Inc, New York and Basel) (1990); pp. 267-316	
	26	PHILLIPS et al., "ELAM-1 Mediates Cell Adhesion by Recognition of a Carbohydrate Ligand, Sialyl-Le", Science 250 (1990); pp. 1130-1132	
	27	ROBBINS and GHIVIZZANI, "Viral Vectors for Gene Therapy", Pharmacology & Therapeutics Vol. 80, No. 1 (1998); pp. 35-47	
	28	SCHOFIELD and CASKEY, "Non-viral approaches to gene therapy", British Medical Bulletin Vol. 51, No. 1 (1995); pp. 56-71	
	29	STYLIANOU et al., "Interleukin 1 Induces NF-KB through Its Type I but Not Its Type II Receptor in Lymphocytes", Journal of Biological Chemistry Vol. 267, No. 22 (1992); pp. 15836-15841	
	30	SZOKA, "Comparative Properties and Methods of Preparation of Lipid Vesicles (Liposomes)", Annual Review of Biophysics and Bioengineering 9 (1980); pp. 467-508	

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Sheet 3 of 3

Application Number	10/616,094
Filing Date	July 8, 2003
First Named Inventor	Martin et al.
Group Art Unit	1636
Examiner Name	KATCHEVES, Konstantina T.
Attorney Docket Number	SQ00151USCON2

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	31	USTER et al., "Insertion of poly(ethylene glycol) derivatized phospholipid into pre-formed liposomes results in prolonged in vivo circulation time", FEBS Letters 386 (1996); pp. 243-246	
	32	WALDMANN, "IMMUNE RECEPTORS: Targets for Therapy of Leukemia/Lymphoma, Autoimmune Diseases and for the Prevention of Allograft Rejection", Annual Review of Immunology 10 (1992); pp. 675-704	
	33	YUAN et al., "Vascular Permeability in a Human Tumor Xenograft: Molecular Size Dependence and Cutoff Size", Cancer Research 55 (1995); pp. 3752-3756	
	34	ZALIPSKY and LEE, "Use of Functionalized Poly(Ethylene Glycol)s for Modification of Polypeptides", Chapter 21, Poly(Ethylene Glycol) Chemistry: Biotechnical and Biomedical Applications (J. Milton Harris, Plenum Press, New York) (1992); pp. 347-370	
	35	ZALIPSKY et al., "Evaluation of a New Reagent for Covalent Attachment of Polyethylene Glycol to Proteins", Biotechnology and Applied Biochemistry 15 (1992); pp. 100-114	
	36	ZALIPSKY, "Synthesis of an End-Group Functionalized Polyethylene Glycol-Lipid Conjugate for Preparation of Polymer-Grafted Liposomes", Bioconjugate Chemistry 4 (1993); pp. 296-299	
	37	ZALIPSKY et al., "Long circulating, cationic liposomes containing amino-PEG-phosphatidylethanolamine", FEBS Letters 353 (1994); pp. 71-74	
	38	ZALIPSKY, "Polyethylene Glycol-Lipid Conjugates", Chapter 9, Stealth Liposomes (CRC Press) (1995); pp. 93-102	

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<b>SUBMISSION UNDER MPEP 609 D</b>  Page 1 of 1	<i>Application Number</i>	10/616,094
	<i>Filing Date</i>	July 8, 2003
	<i>First Named Inventor</i>	Martin et al.
	<i>Group Art Unit</i>	1636
	<i>Examiner Name</i>	KATCHEVES, Konstantina T.
	<i>Attorney Docket Number</i>	SQ00151USCON2

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			Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>		

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		<b>Copy of International Search Report for PCT/US97/18813</b>	

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